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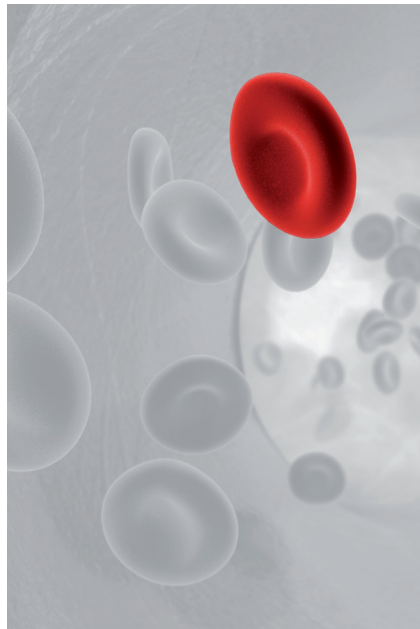
www.gkm-therapieforschung.de

BVMA member since 2017  
Audit passed in 2017



## HISTORY AND MISSION

GKM Gesellschaft für Therapieforschung mbH is an independent, family-owned full-service CRO providing a comprehensive portfolio of clinical research services for the pharmaceutical industry, medical device manufacturers and academia since 1981. Our highly experienced team consults and supports our clients throughout their national or international clinical projects deploying state-of-the-art technology and complying with the very latest standards.



## HIGHLIGHTS

### Key facts:

- ▷ over 800 completed clinical projects
- ▷ wealth of experience in a broad range of indications
- ▷ 74 in-house professionals
- ▷ outstanding personnel continuity
- ▷ high rate of academics and MDs

### International coverage:

- ▷ DACH: 220 freelance CRAs
- ▷ world-wide: long term co-operations with our partner CROs

### Competence:

- ▷ clinical trials and non-interventional studies with pharmaceuticals
- ▷ value dossier writing and consulting, health economic & outcome research
- ▷ clinical and PMCF studies with medical devices

## SERVICES

### Concept & Design

- ▷ medical & statistical consulting
- ▷ feasibility analyses, sample size estimation
- ▷ definition of enrolment criteria, selection of adequate methods of measurement
- ▷ literature research, register searches

### Preparation & Material

- ▷ study protocol / observational plan
- ▷ (e)CRF concept, patient information, informed consent form
- ▷ questionnaires and PROs (electronic or paper-based)
- ▷ regulatory & ethics
- ▷ site recruitment, selection & contracts

### Realization & Support

- ▷ data management & cleaning, query management
- ▷ EDC helpdesk
- ▷ coding (performed by MDs)
- ▷ interim analyses
- ▷ clinical safety & medical surveillance (supervised by MDs)
- ▷ monitoring, study-specific trainings
- ▷ reimbursement management
- ▷ vendor management
- ▷ project & budget management

### Completion & Publishing

- ▷ statistical analysis
- ▷ clinical study report and layman summaries
- ▷ abstract, poster, presentation
- ▷ peer-reviewed publication, journal management
- ▷ study registries publishing